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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/575,580	05/22/2000	Frank McKeon	HMSU-P01-048	1156
25181	7590	10/13/2004	EXAMINER KAM, CHIH MIN	
FOLEY HOAG, LLP PATENT GROUP, WORLD TRADE CENTER WEST 155 SEAPORT BLVD BOSTON, MA 02110			ART UNIT 1653	PAPER NUMBER

DATE MAILED: 10/13/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

09/575,580

**Applicant(s)**

MCKEON ET AL.

**Examiner**

Chih-Min Kam

**Art Unit**

1653

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 09 August 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-3 and 5-13 is/are pending in the application.
- 4a) Of the above claim(s) 1,3 and 5-7 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 8-13 is/are allowed.
- 6) ☒ Claim(s) 2 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

## **DETAILED ACTION**

### ***Status of the Claims***

1. Claims 1-3 and 5-13 are pending.

Applicants' amendment filed August 9, 2004 is acknowledged. Applicants' response has been fully considered. Claims 2 and 8 have been amended. Claims 1, 3 and 5-7 are non-elected inventions and remain withdrawn from consideration. Therefore, claims 2 and 8-13 are examined.

This application contains claims 1, 3 and 5-7 drawn to an invention nonelected with traverse in the response filed September 9, 2002. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

### **Objection Withdrawn**

2. The previous objection of claim 8 is withdrawn in view of applicants' amendment to the claim, and applicants' response at page 4 in the amendment filed August 9, 2004.

### **Rejection Withdrawn**

### ***Claim Rejections - 35 USC § 112***

3. The previous rejection of claims 8-12 under 35 U.S.C. 112, first paragraph, is withdrawn in view of applicants' amendment to the claim, and applicants' response at pages 5-7 in the amendment filed August 9, 2004.
4. The previous rejection of claims 8-13 under 35 U.S.C. 112, second paragraph, is withdrawn in view of applicants' amendment to the claim, and applicants' response at page 7 in the amendment filed August 9, 2004.

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***Informalities***

5. The disclosure remains objected to because the specification cites a nucleic acid having ATCC Deposit No. \_\_\_\_ (e.g., page 27, line 30), however, "ATCC Deposit No." is not provided (see paragraph 4 of the previous Office Action, mailed November 29, 2002).

In response, applicants indicate they will correct the information in the specification and provide appropriate statements regarding ATCC deposit before payment of the issue fee for this application. The objection remains until the information in the specification being corrected.

***Objection to New Matter Added to Specification***

6. The amendment filed August 9, 2004 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: The specification does not indicate a nucleic acid sequence capable of hybridizing under stringent conditions to a nucleotide sequence of SEQ ID NO:2 is at least 80% identical to the nucleotide sequence of SEQ ID NO:2 over its entire length, however, the amended claim 2 recites the new matter.

Applicant is required to cancel the new matter in the reply to this Office Action.

In response, applicants indicate claim 2 has been amended to cite the nucleic acid sequence is at least 80% identical to the nucleotide sequence of SEQ ID NO:2, which is supported by the specification (see page 28, lines 17-23). The response has been considered, however, the argument is not found persuasive because the specification cites the preferred nucleic acids are at least 80% identical to the nucleotide sequence of SEQ ID NO:2, it does not indicate the nucleic acid sequences capable of hybridizing under stringent conditions to a

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nucleotide sequence of SEQ ID NO:2 are at least 80% identical to the nucleotide sequence of SEQ ID NO:2. Note that the nucleic acid sequence that hybridizes under stringent conditions to the nucleotide sequence of SEQ ID NO:2 has the nucleotide sequence complement to SEQ ID NO:2.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claim 2 remains rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 2 is directed to a nucleic acid sequence capable of hybridizing under stringent conditions to SEQ ID NO:2, wherein the nucleic acid sequence is at least 80% identical to the nucleotide sequence of SEQ ID NO:2 over its entire length. The specification indicates a nucleotide sequence which hybridizes under stringent conditions to a nucleic acid shown in SEQ ID NO:2 or complement thereof can be used to isolate nucleic acids corresponding to 5' flanking regions of Csp genes from various animal species (page 32, lines 8-10, 19-20), but it does not indicate these nucleic acid sequences are at least 80% identical to the nucleotide sequence of SEQ ID NO:2. Moreover, the specification does not specify which portion of the nucleotide sequence is at least 80% identical to SEQ ID NO:2. Without guidance on the nucleotide sequence that hybridizes under stringent conditions to SEQ ID NO:2 and is at least 80% identical

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to SEQ ID NO:2, one skilled in the art would not know how to identify this nucleic acid. The lack of representative examples and teachings for the nucleotide sequence that hybridizes to SEQ ID NO:2 and having at least 80% sequence identity to SEQ ID NO:2 as encompassed by the claims, applicants have failed to sufficiently describe the claimed invention, in such full, clear, concise terms that a skilled artisan would not recognize applicants were in possession of the claimed invention.

In response, applicants indicate claim 2 has been amended to cite the nucleic acid sequences that hybridize under stringent conditions to a nucleic acid shown in SEQ ID NO:2, wherein the nucleic acid sequence is at least 80% identical to the nucleotide sequence of SEQ ID NO:2 over its entire length; and there are extensive teachings in the specification about how to identify nucleic acids that fall within the claim limitations, e.g., see pages 31-32 regarding hybridization stringent conditions; see pages 25 and 28 regarding percent identity. The response has been considered, however, the argument is not found persuasive because the specification only cites the preferred nucleic acids are at least 80% identical to the nucleotide sequence of SEQ ID NO:2, it does not indicate the nucleic acid sequences capable of hybridizing under stringent conditions to a nucleotide sequence of SEQ ID NO:2 are at least 80% identical to the nucleotide sequence of SEQ ID NO:2 (see paragraph 6 shown above). Furthermore, the specification does not identify any nucleotide sequence that is at least 80% identical to SEQ ID NO:2 and can hybridize to SEQ ID NO:2. The skilled artisan cannot envision all the contemplated nucleotide sequences for a nucleic acid sequence that is at least 80% identical to SEQ ID NO:2 and hybridizes to SEQ ID NO:2.

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***Conclusion***

8. Claim 2 is rejected, and it appears that claims 8-13 are free of art and allowable.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (571) 272-0948. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached at 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

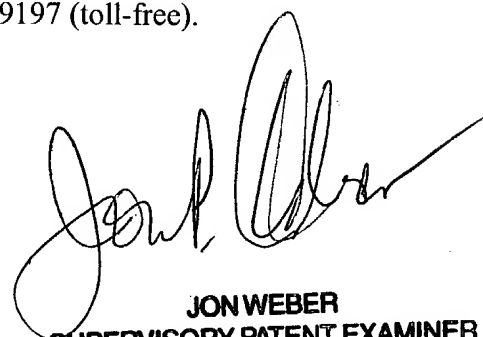
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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Chih-Min Kam, Ph. D.  
Patent Examiner

CMK

CMK  
October 7, 2004



**JON WEBER**  
**SUPERVISORY PATENT EXAMINER**